

REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 2, 4-9 and 13-16 are pending. Claims 3 and 10-12 are cancelled, claims 1, 2, 4 and 6-9 are amended and new claims 13-16 are added without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are patentably distinct from the references cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendments to the claims and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments and remarks are made simply for clarification and to round out the scope of protection to which Applicant is entitled. Support for the amended recitations in the claims and for the new claims is found throughout the specification.

II. THE SECTION 112, FIRST PARAGRAPH, REJECTIONS ARE OVERCOME

Claims 1, 2 and 5-12 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

It is respectfully submitted that the assertions in the Office Action that undue experimentation is required to practice the instantly claimed invention are inaccurate. The Examiner is respectfully invited to review *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988), wherein the Federal Circuit stated at 1404 that:

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is undue, not experimentation.' The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of

guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing the factors summarized in *In re Wands*. These factors include, for example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims; all of which must be taken into account.

Applicant disagrees with the Examiner's contention that "it would require an inordinate amount of experimentation" to, among other things, screen suitable enzymes; and that "reducing agent" is overly broad. Applicant respectfully points out that a skilled artisan would readily understand that suitable enzymes and reducing agents are those that change the conformation of a protein native to the corn or cleave a peptide or disulphite bond of a protein native to the corn (claim 1 as amended). Support can be found on page 6, lines 10-14, of the specification, namely:

The protein may be modified with an enzyme or a reducing agent. Both modification agents have advantages. By the term "modified" in respect of the protein native to corn it is preferably meant that the conformation of the protein is changed. In one aspect by the term "modified" it is preferably meant that a peptide or disulphite bond of the protein is cleaved.

Thus, applying *Wands*, the following, *inter alia*, is clear: the quantity of experimentation necessary to practice the invention is low; the amount of guidance in the specification is high; the nature of the invention is not such that "an inordinate amount of experimentation" is required; the relative skill of those in the art is high; the art is predictable; and the breadth of the claims is narrow. Thus, and contrary to the allegations in the Office Action, undue experimentation would not be necessary to practice the instantly claimed invention.

Consequently, reconsideration and withdrawal of the Section 112, first paragraph, rejections are respectfully requested.

III. THE SECTION 112, SECOND PARAGRAPH, REJECTIONS ARE OVERCOME

Claims 1-12 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The amendments to the claims, without prejudice, have rendered the instant rejection moot.

Further, Applicant disagrees with the allegations that claims 5 and 6 are indefinite. More specifically, and with respect to claims 5 and 6, either the foodstuff has carrageenan or guar gum, or the foodstuff does not have these materials. Thus, clarity does not appear to be at issue.

Even more specifically, Applicant respectfully points out that a claim is definite if the scope of the subject matter embraced by a claim is clear and if the applicant has not otherwise indicated that he intends the claims to be of a different scope. *In re Borkowski*, 164 U.S.P.Q. 642 (C.C.P.A. 1970). The "distinctly claim" requirement of 35 USC § 112, second paragraph, means that the claims must have a clear and definite meaning when construed in light of the complete patent document. *Standard Oil Co. v. American Cyanamid Co.*, 227 U.S.P.Q. 293 (Fed. Cir. 1985). The test of definiteness is whether one skilled in the art would understand the scope of the claim when read in light of the specification. *Morton Int. Inc. v. Cardinal Chem. Co.*, 28 U.S.P.Q.2d 1190 (Fed. Cir. 1993). The degree of precision necessary is a function of the subject matter claimed. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94-95 (Fed. Cir. 1986). Indeed, the Federal Circuit noted in *Hybritech* that:

[I]f the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more' [and] the claims are clearly definite.

Id. at 94 (citing to *Shatterproof Glass Corp. v. Libbey Owens Ford Co.*, 225 U.S.P.Q. 634, 641 (Fed. Cir. 1985)) (emphasis added).

Thus, as the instant claims, read in light of the specification, apprise a skilled artisan of both the utilization and scope of the invention, and as the language **is as precise as the subject matter permits**, the instant claims are definite. A contrary conclusion, as posited by the Office Action, would not only be against public policy, but would also be impermissible as a matter of law. *See Hybritech*, 231 U.S.P.Q. at 95 ("As a matter of law, no court can demand more.").

Consequently, reconsideration and withdrawal of the Section 112, second paragraph, rejection are respectfully requested.

IV. THE SECTION 101 REJECTION IS OVERCOME

Claims 9, 10 and 12 were rejected under 35 U.S.C. §101 for alleged improper claim language. The rejection is traversed.

The amendment to claim 9, and the cancellation of claims 10 ^{through} and 12, without prejudice, render the rejection moot.

Consequently, reconsideration and withdrawal of the Section 101 rejection are respectfully requested.

V. THE ART REJECTIONS ARE OVERCOME

Claims 1-4 and 7-12 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,652,010 to Gimmler et al. ("Gimmler.") And claims 5 and 6 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Gimmler in view of WO 96/39865 to Jensen et al. ("Jensen."). The rejections will be collectively addressed and respectfully traversed.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. See *In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Turning to obviousness, it is respectfully asserted that it is well-settled that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the**

prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Against this background, Gimmler does not anticipate the instant invention. Nor does Gimmler, when combined with Jensen, render the instant invention unpatentable under Section 103.

More specifically, the instant invention is directed to, *inter-alia*, a process for the preparation of a modified masa foodstuff, the process comprising the steps of: (i) preparing a masa by nixtamalisation of corn (ii) contacting a reducing agent or an enzyme with (a) the masa, and optionally (b) the corn prior to nixtamalisation; such that the conformation of a protein native to the corn is changed or such that a peptide or disulphite bond of a protein native to the corn is cleaved, wherein the enzyme is a protease, and wherein the reducing agent is capable of cleaving a disulphite bond of a protein native to the corn is cleaved. Such an invention is neither taught nor enabled by Gimmler. Nor does Gimmler, either alone or in combination with Jensen, teach, suggest or motivate a skilled artisan to practice such an invention. not sequential

Gimmler relates to mass corn-based products made by admixing and heating a coarse ground corn component with water and lime to hydrate the coarse corn component at a temperature below the gelatinization temperature of corn starch, admixing the hydrated coarse corn component with a fine ground starchy component, heating the mixture to form a dough, forming the dough into pieces and baking and/or frying the pieces. More specifically, Gimmler relates to the preparation of masa corn by nixtamalisation. Prior to the nixtamilisation cooking, however, the corn material in Gimmler is treated with proteases. Consequently, after the protease contact, the corn in Gimmler is cooked in alkaline conditions (pH of approximately 11 at temperatures of up to 140°C) to provide the masa material.

The instant invention, by contrast, contacts the masa with the protease or with a reducing agent capable of cleaving a disulphite bond of the protein. This is not the same as Gimmler, which, again, requires treating the corn material with proteases prior to the nixtamalisation cooking. Thus, as Gimmler neither teaches nor enables the instantly claimed invention, the Section 102 rejection must fail as a matter of law.

The Section 103 rejection of claims 5 and 6 is equally defective. Claim 5 is directed to the process of claim 1, wherein the masa foodstuff further comprises carrageenan; and claim 6 is directed to the process of claim 1, wherein the masa foodstuff further comprises guar gum.

Neither claim 5 nor claim 6 are rendered unpatentable by Gimmler, either alone or in combination with Jensen.

Gimmler relates to dough that may be machineable. The document notes that this may be achieved by contacting corn with a protease prior to nixtamalisation. During the nixtamalisation, Applicant asserts that the protease would clearly be inactivated by the conditions of nixtamalisation (pH 11 and temperatures of 140°C). By contrast, the present invention addresses the problems of providing a masa based foodstuff that has improved texture, for example improved rollability, softness and strength, in for example tortillas. To this end, Applicant has provided a process that allows for such improvement in the physical characteristics of masa-based foodstuffs. Such a process is neither taught nor suggested by Gimmler and the problems addressed by the present invention are not those that motivated Gimmler.

Jensen does not remedy the inherent deficiencies in Gimmler. Jensen relates to fat-free corn chips, particularly low-moisture triglyceride fat or digestible fat free cooked corn snack food products. The document lacks, however, any teaching, suggestion or motivating recitation that would lead a skilled artisan to combine its teachings with that of Gimmler, or *vice versa*, in order to practice the instantly claimed invention.

As discussed on page 8 in the instant specification, Applicant has demonstrated that the use of hydrocolloids such as guar gum and carrageenan provide particularly important and unexpected results. For example, carrageenan may improve interaction with proteins and may improve network strength, improve surface texture and maintain water holding capacity of masa-based foodstuffs. And the particular advantages of using guar are highlighted at page 20, line 14 of the present specification.

Applicant respectfully reminds the Examiner that a hindsight attempt at an obviousness rejection is impermissible. Further, Applicant respectfully emphasizes that the only expectation of success is found in Applicant's specification as nowhere in the Gimmler nor Jensen is there any teaching that would lead a skilled artisan to practice the instantly claimed invention.

Again, the Federal Circuit in *In re Fine* was very clear that "obvious to try" is not the standard upon which an obviousness rejection should be based. And as "obvious to try" would be the only standard that would lend the Section 103 rejection any viability, the rejection must fail as a matter of law.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner is respectfully requested, prior to issuance of any paper other than a Notice of Allowance; and the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

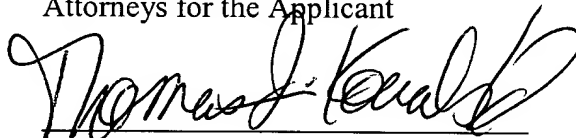
CONCLUSION

In view of the remarks and amendments herewith and those of record, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance, or an interview at a very early date with a view to placing the application in condition for allowance, are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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APPENDIX: MARKED VERSION OF AMENDMENT

Kindly amend the application, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

IN THE CLAIMS:

Please cancel claims 3 and 10-12, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

Please amend claims 1, 2, 4 and 6-9, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, to read as follows:

1. (Twice Amended) A process for the preparation of a modified masa foodstuff, the process comprising the steps of:

- (i) preparing a masa by nixtamalisation of corn; and
- (ii) contacting a reducing agent or an enzyme with

(a) the masa, [and/or] and optionally

(b) the corn prior to nixtamalisation;

[such that a protein native to the corn is modified] such that the conformation of a protein native to the corn is changed or such that a peptide or disulphite bond of a protein native to the corn is cleaved,

wherein the enzyme is a protease, and wherein the reducing agent is capable of cleaving a disulphite bond of a protein native to the corn is cleaved.

2. (Twice Amended) The process of claim 1, wherein the masa foodstuff is selected from the group consisting of corn tortilla, soft [totrilla] tortilla, corn chips, tortilla chips, taco shells, and tamales [, derivatives and mixtures thereof].

4. (Twice Amended) The process of claim 1, wherein the reducing agent is selected from the group consisting of L-[cystein]cysteine, metabisulfite, inactivated yeast extract, [(glutathione)] glutathione, and derivatives and [mistures] mixtures thereof.

6. (Twice Amended) The process of claim 1, wherein the masa foodstuff further comprises guar gum.

7. (Twice Amended) A masa foodstuff [obtainable or obtained by a process as defined in any one of the preceding claims] obtained by the process of claim 1.

8. (Twice Amended) A masa foodstuff comprising a modified protein, wherein

the [unmodified] protein in an unmodified form is native to corn, wherein the conformation of a protein native to the corn is changed or a peptide or disulphite bond of a protein native to the corn is cleaved to provide the modified protein.

9. (Twice Amended) [A method of using a reducing agent or an enzyme to improve the interaction of a protein in a masa foodstuff, wherein the protein is native to the corn] A method of using a reducing agent or an enzyme to provide a higher degree of interaction of a protein in a masa foodstuff with other proteins or other components in the masa foodstuff, when compared to an protein in an unmodified form, the method comprising the steps of

(i) preparing a masa by nixtamalisation of corn

(ii) contacting a reducing agent or an enzyme with

(a) the masa, and optionally

(b) the corn prior to nixtamalisation

wherein the protein is native to the corn, wherein the enzyme is a protease, and wherein the reducing agent is capable of cleaving a disulphite bond of the protein.

Please add new claims 13-16, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

-- 13. (New) The process of claim 1, wherein the reducing agent is selected from the group consisting of L-cysteine, metabisulfite, glutathione, derivatives and mixtures thereof.

14. (New) The process of claim 1, wherein the masa is contacted with the reducing agent.

15. (New) The process of claim 1, wherein the masa foodstuff further comprises a hydrocolloid.

16. (New) The process of claim 1, wherein the masa is contacted with the protease and a xylanase. --